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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/018,892	08/06/2002	Hwei-Sing Kwang	2577-112	8279

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EXAMINER	
PORTNER, VIRGINIA ALLEN	
ART UNIT	**PAPER NUMBER**
1645	

DATE MAILED: 07/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/018,892	KWANG ET AL.	
	Examiner	Art Unit	
	Ginny Portner	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 August 2002*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3/4/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 20-34 have been canceled by preliminary amendment.
Claims 1-19 are pending.

Priority

1. Acknowledgment is made of applicant's claim for priority. ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Please Note: Claim 18 and 19 recite both open and closed language, and therefore are considered to set forth a claim which recites open language with a minimum size fragment defined by the phrase "consisting of" .

3. Claim 18 is rejected under 35 U.S.C. 102(b) as being anticipated by Muller et al (1991). Muller et al discloses an isolated fragment (see page 4768, Table 1, SEF 14, first line of Table) of a S. enteritidis fimbrial protein, the fragment comprising a fragment of SEQ ID No 3, the fragment of SEQ ID NO 3 either being identical to the portion that comprises the amino acid

sequence of SEQ ID NO 3. Muller et al anticipates the instantly claimed invention as now claimed.

4. Claim 18 is rejected under 35 U.S.C. 102(b) as being anticipated by Ogunniyi et al (1994). Ogunniyi et al discloses three isolated fragments (see page 5379, Table 1) of a S. enteritidis fimbrial protein, the fragment comprising a fragment of SEQ ID No 3, the fragment of SEQ ID NO 3 either being identical to or evidencing a conservative substitution in the portion that comprises the amino acid sequence of SEQ ID NO 3. Ogunniyi et al anticipates the instantly claimed invention as now claimed.

5. Claims 1-6,14-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Rajashekara et al (WO98/03656).

6. Rajashekara et al discloses the instantly claimed invention directed to a method of detecting Salmonella enteritidis, the method comprising the steps of:

Contacting (exposed to antibodies against SE, page 6, line 27) a biological sample (see page 7, lines 13-14 "blood or serum"; see page 18, "Eggs were collected for egg yolk antibody detection") with an antigenic fragment (see page 3, line 17 "truncated from of the Sefl4 antigen) of S. enteritidis fimbrial protein (SEP14 fimbrial antigen truncated, see page 11, lines 12-17; see page 6, lines 20-26) under conditions (see page 13, lines 13-27) and Examples 4-6, pages 15-18) sufficient for the formation of an immunological complex between S.enteritidis antibodies present in the sample and said fragment and

Detecting the formation of such a complex (see page 6, lines 27-30) with S.enteritidis antibodies present in the sample, wherein the detecting is specific (see Example 6, page 18).

Instant claim 2: the sample is sera (see page 7, lines 13-14)

the sample is egg yolk (see p. 18, line 21 "egg yolk antibody detection", Ex. 7) .

Instant claim 3: wherein the sample is contacted with a fragment of S. enteritidis fimbrial protein (see page 15, line 22, rSef14 fragment coated latex beads; title "SEF14 fimbrial protein").

Instant claim 4: wherein the fragment is provided as a fusion polypeptide, wherein an additional polypeptide is fused to said fragment (see page 11, lines 11-17 "additional amino acid residues added to the amino terminus to facilitate protein purification and cloning are underlines" see SEQ ID NO 4).

Instant claims 5-6 and 18: wherein the fragment consists essentially of a subfragment of amino acids 21-165 of SEQ ID NO 2 or amino acids 38-165 of SEQ ID NO 2 (see WO98' page 11, SEQ ID No 4, the sequence shares 100% sequence identity with SEQ ID NO 2 and is a fragment of SEQ ID NO 2, and the additional fusion polypeptide amino acids at the N-terminal does not change the basic and novel characteristic of the fimbrial fragment which has the ability to form an antibody/antigen complex with an antibody in a biological sample).

Instant claim 14-17: wherein said fragment is labeled with a detectable label (direct blue bead label, see page 15, lines 22 and 30; an indirect label, anti-chicken antibody coupled with biotin for strep-avidin signal detection (see page 17, lines 13-16; page 6, lines 27-30 to detect anti-SE antibodies with an "enzyme-lined secondary antibody"; page 13, line 22).

Rajashekara et al anticipates the instantly claimed invention.

7. Claims 1, 3,14-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Thorns et al (US Pat. 5,510,241).

8. Thorns et al anticipates the instantly claimed invention directed to a method of detecting Salmonella enteritidis, the method comprising the steps of :

Contacting a biological sample with an antigenic fragment of S. enteritidis fimbrial protein under conditions sufficient for the formation of an immunological complex between S.enteritidis antibodies present in the sample and said fragment and

Detecting the formation of such a complex with S.enteritidis antibodies present in the sample, wherein the detecting is specific (, "an epitope": see abstract col. 11, lines 26-48,col. 3, lines 9-15;, see samples "col. 2, lines 22-26 and lines 44-47; conditions are sufficient for formation of an immunological complex, see col. 6, lines 48-61; labels: see col. 7, lines 31-33, see col. 22, line 48 "peroxidase labeled", see col. 23, lines 1-5 "biotinylated", col. 24, line 25 "immuno-gold labeling"

Instant claim 3: wherein the sample is contacted with a fragment of S. enteritidis fimbrial protein (epitope see col. 11, lines 12-48) .

Instant claim 14-17: wherein said fragment is labeled with a detectable label.

Thorns et al anticipates the instantly claimed invention.

9. Claims 1-2, 7-13 are rejected under 35 U.S.C. 102(b) as being anticipated by van Asten et al (1995).

van Asten et al disclose the instantly claimed method (Western blots, see page 1612, col. 1, paragraph 1) , the method comprising the steps of:

Contacting a biological sample (poly- and monoclonal antisera, page 1611, col. 2, first paragraph) with an antigenic fragment (see page 1612, paragraph 1 and Figure 3) of S. enteritidis flagellin protein (Salmonella enteritidis flagellin, see title, and Figure 3, page 1612 "flagellin fragments") under conditions sufficient for the formation of an immunological complex (see page 1612, col. 1, paragraph 1, middle of paragraph "The

results of these Western blots", and col. 2, page 1612, "also reacted with two polyclonal serum samples") between S.enteritidis antibodies present in the sample and said fragment and

Detecting the formation of such a complex with S.enteritidis antibodies present in the sample, wherein the detecting is specific (see Figure 3, page 1612, "reacted " flagellin fragment and "specific Mab 2").

Instant claim 2: the sample is sera (see sentence bridging pages 1611-1612 "poly- and monoclonal antisera").

Instant claims 7-13: wherein the fragment is a fragment of S.enteritidis flagellin protein (see plurality of fragments defined by regions, and fusion protein fragments, shown in Figure 1, and Figure 3), wherein the fragment is provided as a fusion polypeptide (see page 1612, col. 1, paragraph 2 "expressed the almost complete fliC gene as a fusion protein."; see page 1613, col. 1, paragraph 2 "Our results show that fusion proteins 12E3, KP-2, SS-23, C1-3 and C1-2 contain the g,m epitope") and consists essentially of the amino acids of SEQ ID NO 5, 6, 7, 8 and 9, as the claims permit the presence of additional amino acids that do not change the basic and novel characteristic of binding to a fragment of S.enteritidis flagellin protein the contains the amino acids of SEQ ID Nos 5-9 and the sequence is shown in the shaded part of Figure 1, page 1611 (see ledger, last two lines and structural domains IV-V and VI).

Instant claim 19: an isolated fragment of Salmonella enteritidis flagellin protein, the protein being a sequence which corresponds to said sequence of SEQ Id No 6, the sequence of van Asten et al comprises an amino acid substitution for at least one amino acid in said sequence (corresponds to amino acids 271-338 of native fliC phase I flagellin of S. enteritidis), wherein the fragments of van Asten et al comprise amino acids 271-338 (see Figure 3, page 1612, fragments), which is the range of amino acids of instant SEQ ID NO 6 .

van Asten et al anticipates the instantly claimed invention as now claimed.

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.
11. Aderem et al (PG Pubs 2005/0147627) is cited to show flagellin fragments for induction of an immune response.
12. Clouthier et al (1998) is cited to show periplasmic and fimbrial SefA of Salmonella enteritidis.
13. Dibb-Fuller et al is cited to show an immunoassay based upon fimbriae and flagella for the detection of Salmonella enteritidis (see Table 1).
14. EP 0915158 A2 (Berry et al) is cited to show an assay for the detection of Salmonella based upon an epitope present between amino acids 403-452 of the flagellin protein.
15. He et al (1994) is cited to show a dominant epitope in Region IV of Salmonella fliC flagella.
16. Li et al (1994) is cited to show Salmonella fliC flagellin antigens and amino acids associated with domain IV, and V.
17. Majarian et al(US Pat. 6,130,082) is cited to show mutant region IV flagellin for induction of an immune response to an inserted heterologous epitope inserted into region IV.
18. Marcjanna et al (1998) is cited to show epitopes of type 1 fimbriae of Salmonella enteritidis.
19. Masten et al (1993) is cited to show Flagellar antigens of Salmonella (seeTable 2, page 5362).
20. Muller et al (1991) is cited to show Type 1 fimbriae of Salmonalla enteritidis.
21. Rajashekara et al (Diagn. Microbiol. Infect. Dis. 1998, Vol. 32, pages 147-157 and US Pat. 6,495,334 are cited to show a recombinant fimbrial protein fragment for specific detection of Salmonella enteritidis infection in poultry.
22. Sojka et al (1998) is cited to show epitopes of Salmonella enteritidis fimbriae.
23. Thorns et al (1996) is cited to show an immunoassay for Salmonella enteritidis for fimbrial antigen and flagella.
24. Woodward et al (WO 93/20231 and WO92/06197) are cited to show methods of testing to detect S. enteritidis based upon epitopes present in Salmonella enteritidis fimbria.
25. Zamora et al (February 1999, abstract only) is cited to show a combination of flagellar and fimbrial antigen of S. enteritidis for use in S.enteritidis specific immunological techniques.

26. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (571) 272-0862. The examiner can normally be reached on M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Vgp
July 6, 2005

MARK NAVARRO
PRIMARY EXAMINER